DATE: June 22, 1995 BQC #95-025
NH 16
TO: Nursing Homes Effective Date: 7/1/95

FROM: Judy Fryback, Director
Bureau of Quality Compliance

SUBJECT: **New Nursing Home Survey Protocol and Enforcement Regulations - Second Memo**

In our effort to keep you abreast of changes in the survey protocol and enforcement regulations, we are sending you our second special memo. We trust you found the first one beneficial!

FEATURED TOPICS:

- **GOALS OF THE ENFORCEMENT REGULATIONS**
- **CHANGES IN THE SURVEY PROCESS**
- **DEFICIENCY CATEGORIZATION**
- **REMEDIES**
- **TIPS FOR SURVEY PREPARATION**

Goals of the Enforcement Regulations

The new enforcement regulations and the changes in the survey process redefine the Federal requirements for nursing facilities that participate in the Medicare and Medicaid programs. They also set forth alternative remedies which may be imposed on facilities that do not comply with the Federal participation requirements. The changes are the result of collaborative efforts by Federal and State agencies, consumers, providers and professional organizations who represent nursing homes. The following summarizes the philosophy and goals of the regulatory changes:

- Facilities motivated to remain in compliance;
- Equitable and consistent enforcement;
- Linkage of appropriate remedies to deficiencies;
- No unnecessary processes;
- Reflective, integrated, and focused survey processes.

Changes in the Survey Process

During surveys that start on or after 7/1/95, you will note some changes in the survey process. Detailed information on the process appears in the State Operations Manual (SOM) - Appendix P, which will be forthcoming. Major changes in the seven survey tasks are described below.

Task 1 - Offsite Survey Preparation. There is an increased emphasis on the analysis of facility-specific information. The survey team will identify potential concerns based on survey history and resident census information. Ombudsman information will be reviewed. Concerns will be verified or eliminated once the onsite survey begins.

Task 2 - Entrance Conference/Onsite Preparation. This task remains the same.

Task 3 - Initial Tour. The focus of this task has been enhanced to incorporate an initial evaluation of the facility? s environment, and to further confirm or eliminate concerns identified during the Offsite Preparation. In most cases, it is desirable to have facility staff accompany the survey team on the tour.

Task 4 - Sample Selection. There are now two phases in the sample selection process. Sixty percent of the sample will be identified in Phase One. The Phase One process is based on concerns identified during the Offsite Preparation and the Initial Tour. Other factors to be considered in the selection of the resident sample include: care levels, ability to be interviewed, new admissions, residents with specific waivers, special care needs, etc.

In Phase Two, surveyors decide what concerns need further investigation in order to make deficiency determinations, or to determine 'substandard quality of care. In addition, the survey team will identify and investigate facility performance in at least two areas not routinely surveyed during the standard survey. These areas are listed in the SOM.

Task 5 - Information Gathering. This task includes six areas. The objectives of each include:

5A - *General observations* to observe physical features of the facility's environment that effect residents' quality of life, health, and safety.

5B - *Kitchen/food service observations* to determine if the facility stores, prepares, and serves food according to practices which protect residents from food borne illnesses.

5C - *Resident review* to evaluate resident outcomes related to quality of care and quality of life issues.

5D - *Quality of life assessment* to determine if the facility protects and promotes the rights of residents and assists them in achieving and maintaining their optimum level of well being.

5E - *Medication pass observation* is unchanged.

5F - *Quality assessment and assurance review* to determine if the facility has a quality assessment and assurance committee that identifies problem areas, and develops and implements appropriate plans of action. See first memo.

Task 6 - Information Analysis for Deficiency Determination. All information collected is analyzed to determine if the facility has failed to meet one or more of the regulatory requirements and whether an extended survey is required. A new tool, referred to as the grid, determines the severity/harm and scope/frequency of the deficient practice. The grid is attached to this memo.

Task 7 - Exit Conference. At the conference, the survey team informs the facility of its observations and preliminary findings. There is essentially no change in this task.

Deficiency Categorization

A *deficiency* is a facility's failure to meet a participation requirement specified in the Social Security Act, or in part 483, subpart B (42 CFR 483.5-483.75). Requirements can relate to the resident, specifically, i.e., "*The resident* has the right..." {F221, CFR 483.12(a)}; or relate to a system that must be in place, such as, "The facility must establish an infection control *program*..." {F441, CFR 483.65(a)}. Evidence to support a deficiency is obtained through observation, interviews, and record review.

The survey team will no longer use severity and scope to determine if a federal deficiency exists. Compliance decisions, instead, will be made on the basis of the evidence and regulatory language. If the evidence shows that a requirement was not met for a resident-centered regulation, or that a required system or process was not in place, a deficiency exists.

Only after determining that a federal deficiency exists, will the team consider severity and scope. The team will look at these factors to categorize the deficiency and place it on the grid. To make this decision, the following guidelines are used.

Severity/Harm refers to the degree of impact that a deficient practice has on residents at the facility.

Harm level 4 exists when a situation caused, or is likely to cause serious injury, serious harm, impairment or death to a resident receiving care in the facility AND facility practice establishes a reasonable degree of predictability of similar actions, situations, practices or incidents occurring in the future. Immediate corrective action is needed.

Harm level 3 exists when a situation resulted in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

Harm level 2 exists when a situation results in minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

Harm level 1 exists when a situation has the potential for causing no more than minor negative impact on residents.

If a federal deficiency has multiple examples at different levels of harm, then the most serious level of harm shall be selected along with the frequency associated with that particular level of harm.

Scope/Frequency for federal deficiencies refers to the prevalence of a deficient practice within a facility or to the relative number of residents who were or could have been affected by the deficient practice.

Isolated. If a situation affected or involved a very limited number of residents and/or one of a very limited number of staff, and/or the situation occurred only occasionally or in a very limited number of locations, then the deficiency is classified as "isolated."

Pattern. If a situation involved or affected more than a very limited number of residents, and/or involved more than a limited number of staff, and/or the situation occurred in several locations, and/or the same resident(s) has/have been affected by repeated occurrences of the same practice, then the deficiency is classified as a "pattern." A "pattern" also exists if a deficient practice is widespread within a small subset of all residents in the facility (e.g., residents with gastrostomy tubes).

Widespread. If a situation is pervasive throughout the facility or represents a systemic failure that affected or had the potential to affect a large portion of the facility's residents, then the deficiency is classified as "widespread."

Remedies

A *remedy* is a sanction that serves as an incentive to either bring the facility into or remain in substantial compliance. A remedy can only be applied when a facility is not in substantial compliance. In most cases, it will be imposed only at the time of the verification visit, if the deficiency is uncorrected. Remedies are specific to, and commensurate with, the level of harm and frequency of noncompliance. They fall into three categories.

Category 1 remedies are required when the most serious deficiency from a survey is at a harm level 2 that is "isolated" or a "pattern."

Directed plan of correction is a plan of correction developed by HCFA, the State Agency, or the temporary manager that directs the facility to "do something", i.e., to take action within a specified period of time.

State monitor is an employee or contractor of the State Agency who oversees (onsite as necessary) the correction of deficiencies.

Directed inservice is a plan of correction that requires facility staff to attend training. It is implemented when it is likely that training will correct the deficient practice. The training must usually be given by a well-established outside center, such as a nursing or technical school.

Category 2 remedies are required when the most serious deficiency from a survey is at a harm level 2 that is "widespread", or a harm level 3.

Denial of Payment for new admissions denies payment for all new Medicare and Medicaid admissions. (It does not apply to private-pay residents.)

Denial of Payment for ALL residents denies payment for all new Medicare and Medicaid admissions, as well as all Medicare and Medicaid residents already in the facility. It can be imposed only by HCFA.

Civil Money Penalty (CMP) is a monetary fine, or forfeiture, assessed against a facility for a period in which the facility was not in substantial compliance. Category 2 deficiencies may be assessed a CMP of $50 - $3,000 per day of noncompliance.

Category 3 remedies are required for facilities with a deficiency at harm level 4 (immediate jeopardy).

Temporary manager is a person installed by HCFA or the State Agency to run the facility. A temporary manager has the authority to hire, fire and reassign staff, obligate facility funds, and alter facility procedures. A facility that refuses to relinquish control to a temporary manager will be terminated from Medicare/Medicaid.

Civil Money Penalty (CMP) is an assessment ranging between $3,050 - $10,000 per day of noncompliance.

Termination occurs when a facility is removed from the Medicare and/or Medicaid reimbursement programs.

Federal Regulations
Enclosed is a portion of the Federal Register, Part 483, Requirements for States and Long Term Care Facilities, pages 56,237 - 56,252. For the complete Federal Register, Volume 59, No. 217, dated Thursday, November 10, 1994, write to:

The Superintendent of Documents
P.O. Box 371954
Pittsburgh, PA 15250-7954

Or call the Government Printing Office Access User Support Team at (202)512-1530 between 7AM and 5PM EST, M-F.

Top Tips for Survey Preparation!

1. Establish lines of communication. Identify who the survey team will work with, direct questions to, etc.
2. Begin using the new resident Roster/Sample Matrix to become familiar with it.
3. Make your QAA system work for you! Be proactive. Look at quality of life *and* quality of care issues.

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Attachments:
-Citing Guidelines
-Grid
-Roster/Sample Matrix
-Federal Register

cc:-BQC Staff
-Office of Legal Counsel
-Ann Haney, DOH Admin.
-Kevin Piper, BHCF Dir.
-HCFA, Region V, M. Dykstra
-Illinios State Agency
-Ohio State Agency
-Michigan State Agency
-Indiana State Agency
-Minnesota State Agency
-WI Coalition for Advocacy
-Serv. Employees Inter. Union
-WI Counties Assn.
-WI Health Info. Mgmt. Assn.
-WI Assn. of Homes & Serv/Aging
-St. Med. Society (Comm. Aging...)
-WI Health Care Association
-WI Assn. of Medical Directors
-Admin., Division of Care and Treatment Facilities
-WI Assn. of Hospital SW and Discharge Planners
-Bd. on Aging & Long Term Care
-Bur. of Design Prof., DRL
-LTC BQC Memo Subscribers
-Mark Bunge, BPH
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